SUPPLEMENTARY INFORMATION:

I. Background

Statutory Requirements

Section 121 of the Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA) requires the Secretary of Health and Human Services (the Secretary) to conduct a demonstration project for the Medicare fee-for-service population to demonstrate the impact on costs and health outcomes of applying disease management (DM) services, supplemented with coverage for prescription drugs, to specific Medicare beneficiaries with diagnosed, advanced-stage congestive heart failure, diabetes, or coronary heart disease. This demonstration project should result in a net reduction in aggregate Medicare expenditures. This project may include up to three organizations and cover up to 30,000 lives at a time. The project will last for three years.

Problem

Historically, a small proportion of Medicare beneficiaries has accounted for a major proportion of Medicare expenditures. For example, in 1996, 12.1 percent of all Medicare enrollees accounted for 75.5 percent ($126.1 billion) of all Medicare fee-for-service program payments. Many of these high-cost beneficiaries are chronically ill with certain common diagnoses, and most of the Medicare expenditures for their care are for repeated hospitalizations. During the next 30 years, as the population ages, the number of individuals and estimated cost of care for high-cost beneficiaries is expected to grow dramatically.

In the fee-for-service environment, health care for individuals with chronic illness has often been fragmented and poorly coordinated across multiple health care providers and multiple sites of care. Evidence-based practice guidelines have not always been followed, nor have patients always been taught how best to care for themselves. These shortcomings are particularly true for patients served under reimbursement systems in which providers lack incentives for controlling the frequency, mix, and intensity of services, and in which providers have limited accountability for the outcomes of care.

The vast majority of disease management patients' issues center around a single disease or condition and fall into fundamental problems with their own behavior, access to appropriate prescription drugs, or the disease-specific care they receive. Patient behavior-based problems include poor medication compliance, lack of self-care skills, and lack of adherence to recommended lifestyle changes. Patients' general reluctance to make major adjustments to their ways of life tends to be reinforced when patients are unable to see the direct or immediate benefits resulting from these changes.

Further compounding this problem for Medicare beneficiaries is the fact that Medicare generally does not cover outpatient prescription drugs. Beneficiaries wanting drug benefits have to purchase supplemental insurance, or join a Medicare+Choice plan if they are not already covered under an employer-sponsored retirement plan or a publicly-

funded program, such as Medicaid or the Department of Veterans Affairs. Our research shows that, as of 1998, a majority (73 percent) of Medicare beneficiaries had some drug coverage at one point or another within a given year, and that fewer than half have had uninterrupted coverage for 2 consecutive years. Furthermore, questions remain regarding extent, quality, and comparability of coverage across different programs. Appropriate, effective pharmaceuticals are a key part of a comprehensive treatment program, and effective disease management must include access to appropriate medications.

Provider-related problems include failure to prescribe the most effective medications, poor coordination of care across providers and settings, lack of adherence to disease-specific guidelines based on evidence or expert panels, and inadequate follow-up and monitoring.

Disease Management

The level of interest in, and knowledge about, disease management is growing dramatically. The Institute of Medicine's report, entitled Crossing the Quality Chasm: A New Health System for the 21st Century (published by Health Care Services, National Academy Press in 2001), highlights the challenge of managing chronic conditions within a system that was designed to treat acute illness. Major national organizations, such as the National Disease Management Association (NDMA), have been formed to advance the practice of disease management, and the National Committee for Quality Assurance (NCQA) has just released draft standards for disease management programs for public comment.

Early efforts at disease management occurred mainly in managed care settings, because the plan and the providers had clear incentives to manage care, and the patients were enrolled and "locked into" a delivery system. More recently, a variety of health care organizations, including physician group practices, private insurers, commercial firms, and academic medical centers, have developed programs designed to address the challenges inherent in managing chronic illnesses within the context of a fee-for-service system.

The NDMA, NCQA, and other organizations, such as the National Pharmaceutical Council, have put forward definitions of disease management that contain certain common elements. These definitions view disease management as an approach to delivering health care to persons with chronic illnesses that aims to improve patient outcomes while containing health care costs. These definitions generally focus on persons whose primary health problem is a specific disease, although certain co-morbid conditions are usually addressed as well. Patients with a similar level of severity of the disease tend to face similar problems and therefore receive similar treatment plans. These disease management interventions tend to be highly structured and emphasize the use of standard protocols and clinical guidelines.

There are certain common features in all of these definitions:

- Identification of patients and matching the intervention with need.
- Use of evidence-based practice guidelines.

- Supporting adherence to the plan of care.
- Supporting adherence to evidence-based medical practice guidelines by providing medical treatment guidelines to physicians and other providers, reporting on the patient's progress in compliance with protocols, and providing support services to assist the physician in monitoring the patient.
- Services designed to enhance patient self-management and adherence to his or her treatment plan. Examples of those services are patient education, monitoring and reminders, and behavior modification programs aimed at encouraging lifestyle changes.
- Routine reporting/feedback loop (may include communication with patient, physician, health plan and ancillary providers, and practice profiling).
- Communication and collaboration among providers and between the patient and his or her providers. Related services include team conferences, collaborative practice patterns, and routine reporting and feedback loops. In addition, care managers are often used to relay communication and to coordinate care across providers and by face-to-face encounters with chronically ill patients. Programs that address co-morbid conditions extend their communication efforts to include all of the patient's providers and the entire spectrum of care.
- Collection and analysis of process and outcomes measures.

In addition to these standard features, programs may include use of information technology, for example, specialized software, data registries, automated decision support tools, and call-back systems. Although disease management services usually do not include actual treatment of the patient's condition, many disease management programs augment the services provided in the traditional fee-for-service system by adding such services as comprehensive geriatric assessment, social services, preventive services, transportation, including prevention services and necessary prescription drugs and outpatient medications. The interventions provided go beyond those services generally covered under the Medicare fee-for-service program.

In our recent study (Best Practices in Coordinated Care, Chen et al., March 22, 2000) aimed at investigating and benchmarking case management and disease management efforts, we suggested that case and disease management organizations provide services aimed at addressing one or more of the following goals:

- Improving patient self-care through such means as patient education, monitoring, and communication.
- Improving physician performance through feedback and/or reports on the patient's progress in compliance with protocols.
- Improving communication and coordination of services between patient, physician, disease management organization, and other providers.
- Improving access to services, including prevention services and necessary prescription drugs.

Programs vary in their relative focus on these areas. Some disease management programs may emphasize improving physician use of recommended clinical guidelines; others may focus on providing case managers to support and educate the patient and enhance communication; and still others may emphasize access to additional services.

Other CMS Demonstrations for Management of Chronic Diseases

In the past, we have conducted several demonstrations for case management of chronic illnesses, including the National Long-Term Care Demonstration (Final Report by Kemper et al., May 1966. NTIS Accession No. PB86-229119/AS) and the Medicare Alzheimer's Disease Demonstration Evaluation (Final Report October 1998). The evaluations of these demonstrations found that none of the demonstrations provided sufficient savings to cover the additional costs of case management.

There are several possible reasons for the lack of positive results. First, the most appropriate individuals were not always targeted and enrolled in the demonstration. In many cases, the sites enrolled patients with less severe, and therefore less costly, conditions, making it more difficult to achieve cost savings by avoiding normal utilization patterns of acute or long-term medical care.

We are currently conducting other demonstrations that test either case or disease management, both of which are designed for a smaller number of participants than Medicare's Disease Management Demonstration project. In one ongoing demonstration, Lovelace Health Systems, in Albuquerque, New Mexico, was chosen to operate demonstrations of intensive case management services for high-risk patients with congestive heart failure and diabetes to improve the clinical outcomes, quality of life, and satisfaction with services. The other is a larger scale demonstration authorized by section 4016 of the Balanced Budget Act of 1997 (BBA) to evaluate methods, for example, case management and disease management, that improve the quality of care for beneficiaries with a chronic illness. The "Coordinated Care" demonstration was designed based on the findings of a review of best practices for coordinating care in the private sector. More information about the Coordinated Care Demonstration can be found at www.hcfa.gov/research/coorcare.htm.

The Disease Management Demonstration

In developing this demonstration, we reviewed the work and recommendations of organizations such as the NDMA and NCQA, and examined our prior and current experience with similar demonstrations.

This demonstration differs significantly from its predecessors in that the legislation stipulates that the demonstration must cover all prescription drugs, even those drugs not related to the beneficiary's targeted condition. The legislation also requires each demonstration organization to accept risk or have another entity agree to accept risk if certain Medicare budget provisions are not met, specifically if the demonstration does not reduce aggregate Medicare program expenditures. In addition, this solicitation highlights the need to target the severe and high-cost cases, and to match the intervention to the patient.

For the purpose of this demonstration, disease management is defined as a systematic approach to managing health care that aims to improve patient self-care, physicians' prescribing and treatment practices, communication and coordination of services between

the patient, physician, disease management organization, and other providers, and access to needed services, and incorporates the following features:

- Patient identification, assessment, and enrollment.
- Patient instruction and empowerment regarding self-care.
- Implementation of an appropriate treatment plan based on clinical guidelines.
- Monitoring, feedback, and communication concerning the patient's condition.
- Arranging for and/or providing needed services, including prescription drugs and preventive services.

Disease management programs may also include additional services, such as nurse visits, access to special equipment, and coordination with specialty clinics.